

REMARKS

Claims 12, 14, 15, 17, 21, 22 and 26 are pending and claims 12 is independent. Claims 16, 18-20 and 27-29 have been cancelled at this time. Claims 12 and 14 have been amended. No new matter has been added. For instance, amended claim 12 is supported by at least page 8, lines 20-24, page 9, line 4 – page 10, line 24 and page 11, line 8-12 of the specification. Claim 14 has been amended to remove the recitation of “and/or arabinogalactan”. Thus, no new matter has been added.

Additionally, no new issues have been raised which would require additional search and/or consideration on the part of the Examiner. In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into better form for appeal.

In view of the following remarks, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §§102(b)/103(a) (anticipation/obviousness)

Claims 12, 16, 18, 20, 21 and 26-29 stand rejected under 35 U.S.C. §102(b) as being anticipated by Richards (WO 96/03150A1). Also, claims 12, 18, 21 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kiliaan et al. (WO 01/33975 A1). Further, claims 12, 14-22 and 26-29 stand rejected under 35 U.S.C. §103(a) over Richards or Kiliaan in view of Mehansho et al. (USP No. 6,706,292) or Garti et al. (USP No. 5,847,109). Each of these rejections is respectfully traversed.

While not conceding to the Examiner’s rejections, and in an effort to advance prosecution only, independent claim 12 has been amended to further emphasize the distinctions between the present invention and the cited art.

(i) The Present Invention

Claim 12 of the present invention is directed to a method for ameliorating or treating an inflammatory bowel disease, comprising administering a composition comprising galactomannan as an agent for lowering the activity of myeloperoxidase and TNF- α to a patient suffering from said inflammatory bowel disease, wherein said galactomannan is a degraded galactomannan having an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded galactomannan, and produced by hydrolyzing guar gum with *B*-mannanase.

The present invention achieves unexpectedly superior effects with respect to the administered ingredient and diseases.

Specifically, the test data in Test Examples 1-1 to 1-3 and Figs. 1-3 are encompassed by claims 12, 21 and 26. In fact, the test data demonstrates superior results with respect to the present invention. For instance, the test data demonstrates that galactomannan not only shows histologically ameliorative actions for inflammatory bowel diseases, but also has suppressive action on inflammation, and lowers the activity of myeloperoxidase (MPO) and TNF- α .

Also, the test data in Test Examples 2-1 to 2-4 is encompassed by claims 14, 15, 17 and 22. Again, the test data demonstrates superior results with respect to the present invention. For instance, a review of the results of Tables 6, 8, 10 and 12 reveals that the liquid foods of Examples 2-1 to 2-4 exhibit excellent effects for patients with ulcerative colitis, Crohn's disease, and bowel Behçet disease. In contrast, the liquid foods of Comparative Examples 2-1, 2-3, 2-4, 2-6 and 2-8 are found to show only slight efficacy for patients with ulcerative colitis, Crohn's disease, and bowel Behçet disease, and the liquid foods of Comparative Examples 2-2, 2-5, 2-7, and 2-9 are not found to show any efficacy for any one of the patients.

(ii) Distinctions Between the Present Invention and the Cited Art

As recited in the claims, the present composition requires at least a specific degraded galactomannan which has an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded

galactomannan, and produced by hydrolyzing guar gum with *B*-mannanase. Also, the galactomannan acts as an agent for lowering the activity of myeloperoxidase and TNF- α .

Richards

Richards relates to compositions containing hemicellulose and polyphenols for treating gastrointestinal disorders. However, Richards fails to disclose or suggest that gastrointestinal disorders are the claimed inflammatory bowel disease. At page 8, lines 26-29, Richards states that *examples of gastrointestinal disorders are diarrhea, distension of the abdomen, diverticulitis, constipation and irritable bowel syndrome*. It is noted that these disorders are medically classified different from inflammatory bowel disease (IBD). Also, in one aspect, the claimed inflammatory bowel disease of the present invention is selected from the group consisting of ulcerative colitis, Crohn's disease, and intestinal Behçet disease (claims 12 and 14).

Also, there is no indication in Richards that the galactomannan is a degraded galactomannan having an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded galactomannan, and produced by hydrolyzing guar gum with *B*-mannanase.

Further, Richards fails to disclose or suggest that galactomannan is an agent for lowering the activity of myeloperoxidase and TNF- α .

Therefore, the present invention is not anticipated by the Richards reference.

Kiliaan

Kiliaan relates to nutritional compositions for treating an inflammatory disease of intestine containing galactomannan. However, Kiliaan remains silent about the features that the galactomannan is a degraded galactomannan having an average molecular weight of from 8,000 to 50,000 and a viscosity is 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded galactomannan, and produced by hydrolyzing guar gum with *B*-mannanase.

Also, Kiliaan fails to disclose or suggest that the galatomannan is used for lowering the activity of myeloperoxidase and TNF- α .

Thus, the present invention is not anticipated by the Kiliaan reference.

Richards or Kiliaan in view of Mehansho or Garti.

The deficiencies of Richards or Kiliaan cannot be cured by Mehansho or Garti since Mehansho or Garti also fails to disclose or suggest at least the claimed galactomannan for ameliorating or treating IBD.

In particular, Mehansho discloses an arabinogalactan for preventing constipation.

However, the present invention is directed to a galactomannan for ameliorating or treating IBD. Therefore, the arabinogalactan of Mehansho for preventing constipation is different from the galactomannan of the present invention for ameliorating or treating IBD. Accordingly, even if Mehansho were to be combined with Richards or Kiliaan, a combination thereof cannot achieve the present invention.

Also, Garti generally discloses at col. 3, lines 17-19 that galactomannan is "effective in preventing constipation". However, Garti fails to disclose or suggest ameliorating or treating IBD. Rather, Garti merely refers to "preventing constipation". Further, Garti's galactomannan is derived from fenugreek galactomannan, which is different from the claimed galactomannan derived from guar gum. Therefore, even if Garti were to be combined with Richards or Kiliaan, a combination thereof cannot accomplish the present invention.

As the MPEP directs, all the claim limitations must be taught or suggested by the prior art to establish a *prima facie* case of anticipation or obviousness. See MPEP §§ 2131 and 2143.03. In view of the fact that the cited references fail to teach or fairly suggest the claimed features, a *prima facie* case of anticipation or obviousness cannot be said to exist.

As the reasons discussed above, Applicants respectfully submit that the presently pending claims are neither anticipated by nor rendered obvious over the cited references. The Examiner is therefore requested to withdraw all rejections and allow the currently pending claims.

CONCLUSION


In view of the above remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie Reg. No. 42,874 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,



By _____
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